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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/593,483

10/04/2006

Mitsuru Hasegawa

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KUBOVCIK & KUBOVCIK

SUITE 1105

1215 SOUTH CLARK STREET

ARLINGTON, VA 22202

EXAMINER

JOHNNIE, JOSEPH G

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

07/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/593,483	Applicant(s) HASEGAWA, MITSURU	
	Examiner JOSEPH JOHNNIE	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is responsive to the amendment filed on 3/26/2009. As directed by the amendment: claims 1, 3, and 7 have been amended, and claim 2 has been cancelled. Thus, claims 1 and 3-11 are presently pending in this application.

Response to Arguments

2. Applicant's arguments filed on 3/26/2009 have been fully considered but they are not persuasive.

35 USC § 102

3. In re the limitations of the rejected claims not being disclosed in the cited references, the limitations of a "seal part contacting an inner wall of the barrel and liquid-tightly partitioning the front chamber and the rear chamber, and a bypass communication passage providing communication between the front chamber and the rear chamber, and a bypass communication passage providing communication between the front chamber and the rear chamber in cooperation with the bypass" are disclosed in Higashikawa al (US Patent 5,851,200) in Figs. 17, 18, and 24. Note that the intermediate gasket 91 (fig. 24) includes a seal part 105 (fig. 18) contacting an inner wall of the barrel 88 (fig. 24) and liquid-tightly partitioning the front chamber and the rear chamber, and a bypass communication passage 92 (fig. 17) providing communication between the front chamber and the rear chamber in cooperation with the bypass.

4. In re neither Ohtani nor Higashikawa disclosing a pre-filled syringe which meets the additional limitation of the axial length of the intermediate gasket being longer than that of the bypass, the examiner respectfully disagrees. Upon closer examination,

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Higashikawa discloses an intermediate gasket 91 which appears to be longer than the bypass 116 in figure 24. Accordingly, the § 102(b) rejection is maintained.

35 USC § 103

5. In consideration of the 102(b) rejection being maintained, the examiner also maintains the § 103(a) rejections, but with the primary reference being Higashikawa. The combination of specific features from the inventions of Hughes (US Patent 6,554,792 B2) and Michaels(US Patent No. 5,685,846) with the pre-filled syringe of Higashikawa appears to be proper.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

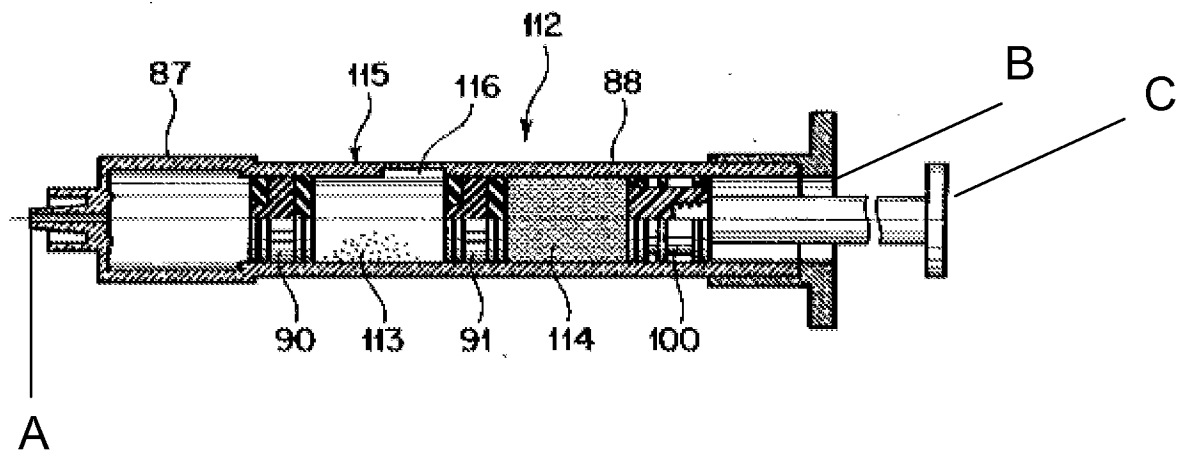
7. Claims 1-4, 6, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Higashikawa et al (US Patent 5,851,200).

8. Re claim 1, Higashikawa discloses a pre-filled syringe comprising: a barrel 88, a tip in which a nozzle A is provided and an open base end B, an intermediate gasket 91 liquid-tightly partitioning an inside of the barrel into a front chamber and a rear chamber, a plunger gasket 100 located in a base end side of the intermediate gasket and sealing the inside of the barrel, and a plunger rod C connected to a base end of the plunger

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gasket, and in which in a tip side of the barrel relative to the intermediate gasket there is formed a bypass 116 protruding outwardly in a radial direction (refer fig. 24 below),

F I G . 24 .



wherein the intermediate gasket (91 from fig. 24) includes a seal part 105 contacting an inner wall of the barrel and liquid-tightly partioning the front chamber and the rear chamber, and a bypass communication passage 92 providing communication between the front chamber and the rear chamber in cooperation with the bypass (refer figs. 17 and 18) and

wherein an axial length of the intermediate gasket 91 is longer than that of the bypass 116 and when an axial length of the bypass 116 is longer than the axial length of the seal part 105 (refer figs 18 and 24).

9. Re claims 3 and 4, Higashikawa discloses a circumferential groove 92 (fig. 17) in the outer wall of the intermediate gasket formed in a circumferential direction of a base end side of the seal part, and a connection passage 106 which is a groove formed in an

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outer wall of the intermediate gasket (fig. 18) connecting the circumferential groove and the rear chamber.

10. Re claim 6, Higashikawa discloses a connection passage that is a conduit formed inside the intermediate gasket (fig. 19).

11. Re claim 9, Higashikawa discloses a tip gasket 90, an intermediate gasket 91, and a plunger gasket 100 in which the combined axial lengths of the three gaskets is less than the length from the tip of the nozzle to the base end of the bypass 116 (fig. 24).

12. Re claim 10, Higashikawa discloses a prefilled syringe wherein the barrel additionally comprises a tip gasket 90 and the front chamber is formed between the tip gasket and the intermediate gasket (fig. 24 above).

13. Re claim 11, Higashikawa discloses a nozzle member, the nozzle formed in the tip of the nozzle member, and the nozzle member including a tip gasket accommodation 87 capable of accommodating tip gasket 90, and a liquid passing passage through which a liquid medicine can pass when the tip gasket has been accommodated in the tip gasket accommodation part (fig. 24 above).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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15. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Higashikawa et al (US Patent 5,851,200) as applied to claims 1 and 3 above, and further in view of Hughes (US Patent 6,554,792 B2).

16. Re claim 5, Higashikawa discloses all of the claimed invention except for a connecting passage which is a spiral groove formed in the outer wall of the intermediate gasket. However, Hughes teaches the use of a spiral groove (fig. 6) in order to permit rapid and uniform filling of a spatial network with an agent (col. 5, lines 24-37).

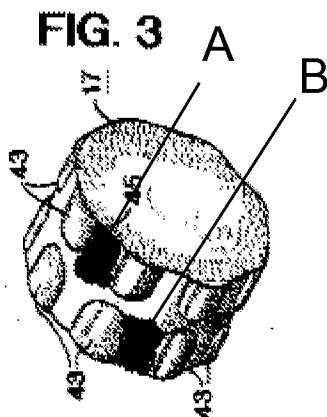
Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Higashikawa's invention such that the connection passage is a spiral groove, as suggested and taught by Hughes, for the purpose of permitting rapid and uniform filling of the communication passage (col. 5, lines 24-37).

17. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higashikawa et al (US Patent 5,851,200) as applied to claim 1 above, and further in view of Michaels (US Patent No. 5,685,846).

18. In re claim 7, Higashikawa discloses all of the claimed invention except for a bypass communication passage comprising at least one first groove extending from an intermediate gasket tip side in a base end direction and at least one second groove extending from an intermediate gasket tip side in a tip direction with the tips of the second groove relative to the base end of the first groove. However, Michaels teaches the use of a bypass communication passage comprising at least one first groove extending from an intermediate gasket tip side in a base end direction (element B of figure 3 below) and at least one second groove extending from an intermediate gasket

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base end side in a tip direction (element A of figure 3 below), with the tips of the second groove relative to the base end of the first groove for the purpose of permitting flow of liquid from a proximal chamber to a distal chamber upon depression of a plunger (column 2, lines 40-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention was made to modify the Higashikawa's reference to include the first and second grooves as suggested and taught by Michaels, in order to permit the flow of liquid from a proximal chamber to a distal chamber upon depression of a plunger (column 2, lines 40-49).



19. In re claim 8, Higashikawa discloses all of the claimed invention except for establishing the relationship between the length of the bypass in a circumferential direction, a_2 and the length of the distance between the first and second grooves b_2 where $a_2 > b_2$. However, Michaels teaches the sizing of bypass channels in order to allow the bypass channels to engage with a sealing ring (column 3, line 60 - column 4, line 37), and control the mixing of two agents (column 4, lines 47-60). Similarly, it would have been an obvious matter of design choice to make the length of the bypass in the

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circumferential direction greater than the length of the distance between the first and second grooves, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Higashikawa's invention to adjust the length between the first and second grooves to be less than the length of the bypass in the circumferential direction, as suggested and taught by Michaels, for the purpose of the grooves engaging the bypass and controlling the mixture of two agents (column 3, line 60 - column 4, line 37).

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOSEPH JOHNNIE whose telephone number is (571)270-7838. The examiner can normally be reached on 10:00AM-6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOSEPH JOHNNIE
Examiner
Art Unit 3767

/JOSEPH JOHNNIE/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767

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